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EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/710,262

Applicant(s)

ROSENBERG ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Application Status*

1. In response to the previous Office action, a written restriction requirement (Paper No. 20, mailed on February 19, 2003), Applicants filed an election and amendment received on April 30, 2003 (Paper No. 23); the election was not completely response. A subsequence election (Paper No. 25) elected the invention to be examined completely. Said amendment amended Claims 1-9. Claims 1-16 are pending in the instant Office action.

### *Election*

2. In the combination of Paper Nos. 23 and 26, Applicants' election of DNA claims (SuperGroup A) relating to SEQ ID NO:1 (Group I) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Contrary to Applicants' assessment (see Paper No. 26 received June 11, 2003), election of SEQ ID NO:1 is *not* a species election, but an election of **Group**. No election of species was set forth in the written restriction requirement (Paper No. 20). Claims relevant to the elected subject matter, as amended, as Claims 1-8 and 10-14. Claims 9 and 15-16 are withdrawn from consideration as non-elected inventions. Subject matter in Claims 1-8 and 10-14 relating to other than SEQ ID NO:1 is also withdrawn from consideration as non-elected inventions. Thus, Claims 1-8 and 10-14, as they relate to SEQ ID NO:1, will be examined herein.

### *Priority*

3. The instant application is granted priority for the continuation of U.S. non-Provisional Application No. 09/240,537 filed January 29, 1999 as requested in the transmittal sheet.

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***Information Disclosure Statement***

4. The information disclosure statement filed on November 10, 2000 (Paper No. 4) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. The Examiner notes that the Varon reference has an incomplete citation, which was fixed by the Examiner. No action is required by Applicants.

***Drawings***

5. The drawings are considered informal for the reasons detailed in the attached copy of PTO Form 948. Appropriate correction is required in response to the instant Office action and may not be held in abeyance (see 37 C.F.R. § 1.85(a)).

***Compliance with the Sequence Rules***

6. By virtue of the sequence listing filed on November 5, 2002 (Paper No. 18) listing 20 sequences in the listing, citing sameness and no new matter, the instant application now fully complies with the sequence rules. However, a new matter issue is raised below with respect to this filing of the sequence listing.

***Objections to the Specification***

7. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---DNA Encoding a Polypeptide Required for Biosynthesis of the TA Antibiotic---

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8. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species,

*Myxococcus xanthus*, for completeness.

9. The specification is objected to for lacking continuity data in the first paragraph. The instant application claims the benefit of U.S. non-Provisional Application No. 09/240,537 filed on January 29, 1999, now abandoned; however, no citation is noted in the first paragraph.

Appropriate amendment to the specification is required (see M.P.E.P. § 201.11).

The Examiner notes that an appropriate amendment was attempted in a paper filed as a preliminary amendment on November 11, 2000 (Paper No. 3); however, that amendment was not entered by virtue of an unclear citation as to its intended location.

10. The specification is objected to for the following discrepancies:

- a) On page 3, line 17, the specification is amended to read "SEQ ID NO:2"; however, both SEQ ID NOs: 2 and 20 are DNAs. Applicants are requested to check this citation.
- b) On page 4, lines 12-14, 42kB of sequence are described by way of SEQ ID NOs: 1-17, while only SEQ ID NO:2 is a DNA, and SEQ ID NO:2 is only about 7.2 kb.
- c) On pages 4-6, the description of the genes in Figure 1 would be greatly facilitated by listing which genes are in the 20 kb piece (apparently taA-taN and taR1-taR3) and which gene is in the 8-10 kb piece (apparently ta1).
- d) On page 10, the Varon citation is incomplete.

Clarification and/or correction for all of the above are required.

11. The specification is objected to for the removal of useful information in pages 11-21, which was the originally intended sequence listing. In these pages, a functional description of

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each of the disclosed polypeptides is taught; this is very useful information to the public and should remain in the specification in the form of a table, for example.

12. The specification is objected to for being confusing with respect to the sequence listing. The sequence listing contains 20 sequences. Only SEQ ID NO:2 is *clearly* referred to in the specification as presently amended. It is unclear why said sequences are in the sequence listing if they are not all clearly described in the specification. All SEQ ID NOs in the sequence listing must be described in the specification. Appropriate correction is required. The Examiner suggests a Table, as suggested above, to adequately describe all the disclosed sequences in the listing.

13. The amendment filed November 6, 2002 (Paper No. 18) is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- a) SEQ ID NO:10 is originally disclosed as 82 amino acids on page 15 of the specification, but in the sequence listing filed as Paper No. 18, this sequence has 83 amino acids.
- b) SEQ ID NO:19 is originally disclosed as 423 amino acids on page 17 of the specification, but in the sequence listing filed as Paper No. 18, this sequence has 424 amino acids.

Applicant is required to cancel the new matter in the reply to this Office Action or to explain the discrepancy, particularly noting that accompanying Paper No. 18 was a sworn statement attesting that no new matter had been added.

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***Objections to the Claims***

14. Claims 1-8 and 1-14 are objected to for containing non-elected subject matter. The instant claims will be examined as if they reference only SEQ ID NOs: 1 and/or 2 (the elected Group).

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 2-8 and 10-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 2, the phrase “as set forth in and one of” is wholly unclear. For purposes of compact prosecution, the Examiner will assume this is a typographical error that should read ---as set forth in any one of---. Clarification and/or amendment are required.

16. Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “encoded polypeptide” is clear with respect to Claim 1 since said claim clearly describes the DNA product as encoding a polypeptide. However, Claim 8 is unclear with respect to Claim 2 wherein only a SEQ ID NO is named and no encoding polypeptide is mentioned. Clarification is required.

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17. Claims 10-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are confusing based on their requiring the DNA of Claim 7, wherein Claim 7 is drawn to an *E. coli* host cell. Clarification and/or amendment are required.

18. Claims 11-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 11, the term "suitable" is unclear. Suitable for expression? Suitable for transformation only? The metes and bounds are unclear. Clarification is required.

#### *Art of Record*

19. The following are cited to complete (or comment on) the record for the instant application; they are not used for prior art rejections against the examined claims.

- a) Paitan *et al.* The First Gene in the Biosynthesis of the Polyketide Antibiotic TA of *Myxococcus xanthus* Codes for a Unique PKS Module Coupled to a Peptide Synthetase. *J. Molecular Biology* (Feb, 1999) 286: 465-474. This art teaches SEQ ID NO:2 but is not available as prior art.
- b) Varon *et al.* Trans-acting regulation of antibiotic TA genes in *Myxococcus xanthus*. *FEMS Microbiology Letters* (1997) 155: 141-146. This art teaches genes encoding the accessory proteins disclosed in the instant application (pPYCC44); however, these genes are not part of the elected subject matter.
- c) Tolchinsky *et al.* Use of *Tn5lac* to Study Expression of Genes Required for Production of the Antibiotic TA. *Antimicrobial Agents and Chemotherapy* (1992) 36(10): 2322-2327. This art teaches several strains and inserts involved in TA biosynthesis, but none can be reasonably concluded to encode the claimed *tal* gene product.
- d) Varon *et al.* 1992 (see IDS). This art teaches several strains and inserts involved in TA biosynthesis, but none can be reasonably concluded to encode the claimed *tal* gene product.



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*Conclusion*

20. Claims 1-8 and 10-14 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

August 9, 2003

